DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

941004

WARNING LETTER

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

June 17, 2003

Ms. Hahn T. Bui
Tuna Express Company
512 Stanford Avenue
Los Angeles, CA 90013

W/L 41-03

Dear Ms. Bui:

The Food and Drug Administration conducted an inspection of your facility located at 512 Stanford Avenue, Los Angeles, CA on April 23-24, 2003. At the conclusion of the inspection you were issued a Form FDA-483 which listed a number of your firm's deviations from the Seafood HACCP regulations, 21 C.F.R. Part 123 and from current Good Manufacturing Practices regulations, 21 C.F.R. Part 110. These conditions cause the products processed in your facility to be adulterated within the meaning of Section 402(a)(4) of the Food, Drug, and Cosmetic Act (the Act) in that they were prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. You can find this Act, the current Good Manufacturing Practices regulations and the seafood HACCP regulations through links in FDA's home page at www.FDA.GOV.

The following is a list of the deviations from the seafood HACCP regulations observed during the April 23-24, 2003 inspection:

1. You must have a HACCP plan that at a minimum, lists the critical control points to comply with 21 C.F.R. § 123.6(c)(2). A critical control point is defined in 21 C.F.R. § 123.3(b) as a "point, step, or procedure in a food process at which control can be applied and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels." However, your firm's HACCP plan for "fin fish" does not list the critical limit at "storage" critical control point to control pathogen growth and toxin formation. The plan should identify the respective critical limit, monitoring, corrective action(s) and records.

2. You must implement the monitoring procedures and recordkeeping system that you have listed in your HACCP plan, to comply with 21 C.F.R. § 123.6(b). However, your firm did not record monitoring observations at the "Receiving" critical control point to control pathogen growth and toxin formation in the "Fin Fish."

3. You must adequately monitor sanitation conditions and practices during processing to comply with 21 C.F.R. § 123.11(b). However, your firm did not monitor the maintenance of hand washing, hand sanitizing, and toilet facilities; safety of water that comes into contact with food or food contact surfaces with sufficient frequency to ensure control as evidenced by: (1) an open-ended hose observed lying on the wet floor of the processing room; (2) the processing room did not have a hand sanitizer for employees to use; (3) the men's restroom did not contain toilet paper and hand sanitizer; and (4) the women's restroom did not contain toilet paper and the hand dryer did not operate.

4. You must correct sanitation deficiencies detected during monitoring in a timely manner, to comply with 21 C.F.R. § 123.11(b). However, your firm did not correct the following sanitation deficiencies: (1) the processing room did not have a hand sanitizer for employees to use; (2) the men's restroom did not contain toilet paper and hand sanitizer; (3) the women's restroom did not contain toilet paper and the hand dryer did not operate; and (4) an open-ended hose was observed lying on the wet floor of the processing room.

5. You must maintain sanitation control records that, at a minimum, document monitoring and corrections to comply with 21 C.F.R. § 123.11(c). However, your firm did not maintain sanitation monitoring records for the safety of water that comes into contact with food or food contact surfaces, safety of water used to manufacture ice, condition and cleanliness of food contact surfaces, prevention of cross-contamination, maintenance of hand washing, hand sanitizing, and toilet facilities, protection of food, food packaging material, and food contact surfaces from adulteration with contaminants, proper labeling, storage, and use of toxic compounds, control of employee health conditions that could result in microbiological contamination, and exclusion of pests from the facility required for the processing of your ready-to-eat tuna.

6. You must have a product specifications that are designed to ensure that the fish and fishery products you import are not injurious to health, to comply with 21 C.F.R. § 123.12(a)(2)(i). However, your firm does not have adequate HACCP import verification that includes product specification and affirmative steps for the fish and fishery items imported from Vietnam.

7. Failure to sign and date the HACCP plan either by the most responsible person onsite at the processing facility or by a higher level official of the processor, upon initial acceptance, and after a modification to the plan, as required by 21 C.F.R. § 123.6(d). Specifically, the HACCP plan for "Fin Fish" was not signed or dated.

Our investigator observed the following deviations from the current Good Manufacturing Practice regulations during the April 23-24, 2003 inspection:

1. Failure to clean food-contact surfaces as frequently as necessary to protect against contamination of food, as required by 21 C.F.R. § 110.35(d). Specifically, on 4/23/03 the tables and the cutting boards in the processing room were observed to be sprayed with hot water after use. The firm did not use a sanitizer to clean the food-contact surfaces. Bleach sanitizers are used every other day. The cutting boards were observed to have deep cuts. Brown debris was embedded within these deep cuts.

2. Suitable outer garments are not worn that protect against contamination of food and food contact surfaces, as required by 21 C.F.R. § 110.10(b)(1). Specifically, two employees were observed wearing street clothes while processing fresh tuna fillets.

3. Failure to wear hair nets where appropriate, as required by 21 C.F.R. § 110.10(b)(6). Specifically, three employees were observed wearing baseball caps and no hair nets while in the processing room.

This letter may not list all of the deviations in your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations, 21 C.F.R. Part 110.

You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act an all applicable regulations.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

Please notify this office in writing within fifteen (15) days from your receipt of this letter, of the specific steps you have taken to completely correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the date by which correction will be completed. You may wish to include in your response documentation such as HACCP plans, corrective action forms, monitoring forms and recent monitoring data or other useful information that would assist us in evaluating your corrections.

Your written reply should be addressed to:

Acting Director, Compliance Branch
US Food and Drug Administration
19900 MacArthur Boulevard, Suite 300
Irvine, California 92612-2445

If you have any questions regarding any issue in this letter, please contact MaryLynn Datoc, Compliance Officer, at telephone number 949-798-7628.

Sincerely,

Scott A. Gaff for

Alonza E. Cruse
District Director

cc: State Department of Public Health
Environmental Health Services
Attn: Chief Food and Drug Branch
601 North 7th Street, MS-357
P. O. Box 942732
Sacramento, CA 94234-7320